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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/600,012

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Jeffrey Owen Phillips

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7590

08/20/2002

William B Kircher
Shook Hardy & Bacon
One Kansas City Place
1200 Main Street
Kansas City, KS 64105-2118

EXAMINER

KREMER, MATTHEW J

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 08/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/600,012

Examiner

Matthew J Kremer

Applicant(s)

PHILLIPS ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because “my” in line 2 should be “by”. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites the limitations “the tip” in line 9 and “the changes” in line 11 in which there are insufficient antecedent bases. Claim 15 recites the limitation “the intracranial pressure” in line 3 in which there is insufficient antecedent basis. Claim 18 recites the limitation “said data” in line 3 in which there is insufficient antecedent basis. Claim 21 recites the limitations “the tip” in line 9 and “the changes” in line 11 in which there are insufficient antecedent bases. Claim 28 recites the limitation “said data” in line 3 in which there is insufficient antecedent basis. Claim 31 recites the limitations “the tip” in line 6 and “the monitoring” in line 7 in which there are insufficient antecedent bases. Claim 36 recites the limitations “the tip” in line 7 and “the monitoring” in line 8 in which there are insufficient antecedent bases.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 10-11, 14, 21, 24, 31, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,117,836 to Millar. Millar discloses a method of implanting a ventricular catheter having one end residing in the ventricular region and the other end exiting the cranial region at a distal location. (Abstract of Millar). Millar discloses an opening in the skull 14 and the insertion of the catheter 26 into a region of cerebral spinal fluid 22. (Fig. 1 of Millar). The catheter 26 has openings 28 which allow intracranial fluid to pass from brain 20 to the inside of the catheter. (column 6, lines 9-18 of Millar). A transducer 40 is placed in catheter 26. (column 6, lines 19-41 of Millar). In regard to claim 11, the catheter is implanted in the ventricular region. (Abstract of Millar). In regard to claims 14 and 24, the sensor is locked in the catheter by the use of an adapter 54. (Fig. 5 of Millar).

6. Claims 10-12, 21-22, 25, 31-33, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,903,707 to Knute et al. (cited by Applicant). Knute teaches a catheter assembly which is inserted through an opening in a skull to monitor a parameter of the brain. (column 1, lines 42-45 of Knute et al.). Pressure is monitored by a transducer which is inserted into the catheter. (column 2, lines 21-27 of

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Knute et al.). The catheter 21 includes a rigid portion 33 adapted to fit slidably within the opening 29 in the bolt means 17 and a flexible portion 35 adapted to penetrate into a ventricle 37 of the brain. The flexible portion 35 has an opening 39 from the lumen 31 to an exterior surface 41 of the catheter 19 for communication between the lumen 31 and any fluid 43 (including cerebrospinal fluid) adjacent the catheter 19. (column 3, lines 22-39 of Knute et al.). In regard to claims 12 and 22, the bolt means 17 and clamping means 21 are used to fix the catheter to the opening in the skull. (column 3, lines 10-21 of Knute et al.). In regard to claims 25, 33, and 38, there are means for draining fluid from the brain. (column 4, lines 15-20 of Knute et al.).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 15-20, 25-30, 32-35, and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,117,836 to Millar as applied to claims 10, 14, 21, 24, and 31 in view of U.S. Patent 4,904,237 to Janese. In regard to claims 15 and 25, the transducer is used to measure chemical content, pressure, hemodynamics, and waveform responses. (column 4, lines 28-32 of Millar). Millar does not teach an apparatus or method for draining the cerebral spinal fluid. Janese teaches an

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apparatus which treats disease states by filtration, cooling, adjusting hydrogen ion concentration and returning the cerebrospinal fluid or artificial cerebrospinal fluid to the spinal canal. This apparatus and procedure can be used in any vertebrate for the treatment of brain and spinal cord injuries. Furthermore, the apparatus and method is used in conjunction with monitoring the physical and chemical parameters of the cerebrospinal fluid. (column 1, lines 7-17 of Janese). Such a device will increase the chance of survival after an aneurysm has ruptured. (column 1, line 35 to column 2, line 16 of Janese). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Millar to include the filtration, cooling, adjusting hydrogen ion concentration, and returning of the cerebral spinal fluid as disclosed by Janese since the chance of survival after an aneurysm has ruptured will increase. In regard to claims 16, 26, and 34, Millar does not teach that a transducer is used to monitor pH, partial oxygen pressure, temperature, or carbon dioxide concentration. Janese teaches that parameters of interest in cerebral spinal fluid include pH, temperature, and pressure. Such parameters are of the type suggested by Millar as chemical content and hemodynamics. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a transducer for measuring pH and temperature as disclosed by Janese in the invention of Millar since Millar teaches that the transducer can measure chemical content and hemodynamics and Janese teaches such transducers. In regard to claims 17 and 27, Janese teaches that the pH and other parameters are monitored to detect any dangerous or significant changes in the medical management of the patient. These

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changes alert the technician that something is wrong with the system or the patient which requires immediate attention. (column 8, lines 50-60 of Janese). The arrangement inherently includes comparing the reading with a base line or threshold. In regard to claims 19-20 and 29-30, it is known in the art that diagnosis, management, and/or treatments of cerebral spinal fluid takes place during intra-cranial arterial vasospasm, subarachnoid hemorrhage, trauma to the brain and spinal cord, and fetal intra-cranial hemorrhage. (column 10, lines 23-35 of Janese). The purpose of the invention is to function as a diagnostic tool at such times. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the combination at times of arterial vasospasm, subarachnoid hemorrhage, trauma to the brain and spinal cord, and fetal intra-cranial hemorrhage since it is the purpose of the combination to provide diagnostic aid at these times. The combination does not disclose monitoring within the initial 24 or 48 hours of the trauma. It is known in the art that the monitoring and treatment of patients after a trauma is routinely performed to improve the patient's chances for survival. The patient's survival will particularly increase if monitoring and treatment are initiated as soon possible after the trauma. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus of the combination to include initiating monitoring and treatment within 24 hours from the head trauma since the immediate attention will improve the patient's chances for survival. In regard to claims 32-33 and 37-38, the catheter 40 with sensor tip is one lumen. (column 6, lines 19-24 of Millar). Catheter 26 is another lumen in which the cerebral spinal fluid would

be drained for the combination. Alternatively, another lumen for draining the cerebral spinal fluid could be introduced into catheter 26. In regard to claims 35 and 40, the combination includes equipment for interpreting signals and storings data. (column 7, lines 16-23 of Janese).

9. Claims 13 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,117,836 to Millar as applied to claims 10 and 21 in view of U.S. Patent 5,830,188 to Abouleish. Millar does not teach inserting the catheter into a region of cerebral spinal fluid until expression of the fluid indicate that the catheter has reached the cerebral ventricle. It is well known in the art that expression of cerebral spinal fluid is an indication that the catheter is properly inserted in a region of cerebral spinal fluid. (column 5, lines 25-33 of Abouleish). Such a method provides the necessary information for the caregiver to carry out the insertion step as required by Millar. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use expression of the cerebral spinal fluid to indicate that the catheter is properly positioned since such a method provides the necessary information for the caregiver to carry out the insertion step as required by Millar.

Response to Arguments

10. Applicant's arguments with respect to claims 1-9 have been considered and Examiner agrees that they are moot due to Applicant's cancellation of claims 1-9. As

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far as the applicability of Applicant's arguments with respect to claims 10-40, they have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer
Assistant Examiner
Art Unit 3736
August 13, 2002



ERIC F. WINAKUR
PRIMARY EXAMINER